

REMARKS

STATUS OF CLAIMS

Claims 1, 5-9, 11-16, 18-20, 22, 23, and 28-32 are presently pending in the application.

Claims 1, 9, 11-16, 18, 19, 22 and 23 have been amended. Claim 1 has been amended to recite a particular embodiment; support for this change may be found in original claims 4, 10, paragraph [0030] and [0050]. Claims 9, 11-16, 18, 19, 22 and 23 have been amended to provide internal consistency between the claims and to change the dependency of Claims 1, 22 and 23 to Claim 1. Claim 15 has also been amended to add more particular description; support for this change may be found in the specification, for example, in paragraph 33 et seq. Claim 18 has also been amended to add further description; support for this change may be found in the specification, for example, in paragraph 81. Claims 2-4, 10, 17, 21 and 24-27 have been cancelled. New Claims 28-29 have been added, support for which can be found in the specification, for example, in paragraph 51. New Claims 30-31 have been added, support for which can be found in the specification, for example, in paragraph 52. New Claim 32 has been added based on the subject matter deleted from Claim 1. No new matter has been added.

Thus, Claims 1, 5-9, 11-16, 18-20, 22, 23, and 28-32 are presented for examination.

WITHDRAWN REJECTIONS

Withdrawal of Rejection Under 35 U.S.C. §102(b) Based on CRIVELLO

Applicant acknowledges with thanks the withdrawal of the rejection under 35 U.S.C. § 102(b) based on Crivello et al (U.S. Patent No. 4,584,356) (“CRIVELLO”).

Withdrawal of Rejection Under 35 U.S.C. §102(b) Based on KUMAR

Applicant acknowledges with thanks the withdrawal of the rejection under 35 U.S.C. § 102(b) based on Kumar et al (U.S. Patent No. 5,057,619) (“KUMAR”).

Withdrawal of Rejection Under 35 U.S.C. §103(a) Based on CRIVELLO in View of KAMATH

Applicant acknowledges with thanks the withdrawal of the rejection under 35 U.S.C. § 103(a) based on CRIVELLO in view of Kamath et al (U.S. Patent No. 6,335,029) (“KAMATH”).

Withdrawal of Rejection Under 35 U.S.C. §103(a) Based on CRIVELLO in View of ZULOSKY

Applicant acknowledges with thanks the withdrawal of the rejection under 35 U.S.C. § 103(a) based on CRIVELLO in view of Zulosky (U.S. Patent No. 4,616,064) (“ZULOSKY”).

Withdrawal of Rejection Under 35 U.S.C. §103(a) Based on KUMAR in View of ZULOSKY

Applicant acknowledges with thanks the withdrawal of the rejection under 35 U.S.C. § 103(a) based on KUMAR in view of ZULOSKY.

NEW REJECTIONS

Rejection Under 35 U.S.C. §103(a) Based on KAMATH

Claims 1, 4-9, 17 and 21 are rejected under 35 U.S.C. § 103(a) based on KAMATH. This rejection is respectfully traversed and further is believed to be moot in view of the amendments to the Claims.

For a proper obviousness rejection under 35 U.S.C. 103, the differences between the subject matter sought to be patented and the prior art must be such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. 35 U.S.C. §103. The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. MPEP 2141. “ ‘[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.’ ” *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, 82 USPQ2d 1385 (2007), quoting *In re Kahn* , 441 F.3d 977, 988, (Fed. Cir. 2006). It should be noted that the prior art reference (or references when combined) must teach or suggest all the claimed features. “When determining whether a claim is obvious, an examiner must make ‘a searching comparison of the claimed invention – *including all its limitations* – with the teaching of the prior art.’ ... Thus, ‘obviousness requires a suggestion of all limitations in a claim.’ ...” *Ex parte Wada and Murphy*, BPAI Appeal No. 2007-3733, January 14, 2008 (emphasis in original) (citations omitted). In addition, there must be a reasonable expectation of success. See MPEP 2143.02.

KAMATH describes an:

Implantable medical device having a structure adapted for introduction into a patient wherein the structure is composed of a base material positioned over the structure. The implantable medical device further includes at least one composite layer of a bioactive agent and a polymer material and at least a barrier layer positioned over the composite layer and being of thickness adequate to provide a controlled release of the bioactive agent. The barrier layer being applied by a low energy plasma polymerization process which includes placing the device with the at least one composite layer in a plasma chamber and introducing at least one monomer gas.

(Abstract)

In contrast to KAMATH:

The present invention describes:

An implantable or insertable medical device comprising (a) a therapeutic agent and (b) a polymeric carrier region that comprises said therapeutic agent and which releases said therapeutic agent upon administration to a patient, said polymeric carrier region comprising a silicone block copolymer comprising a plurality of siloxane units and a plurality of non-siloxane units, said block copolymer comprising (i) a block of said siloxane units selected from a polydimethylsiloxane block, a polydiethylsiloxane block, a polymethylethylsiloxane block and a polymethylphenylsiloxane block and (ii) a block of elevated T_g non-siloxane units, wherein the polymeric release region is in the form of a coating layer that covers all or a part of said medical device.

The Examiner states that KAMATH “suggests that the carrier layer can be made of siloxane polymers comprising siloxane units” (Office Action, page 7) but also notes that KAMATH “does not expressly teach that the copolymer of the implantable medical device is a block copolymer comprising siloxane units and a block of elevated non-siloxane units.” (Office Action, page 8). Thus, KAMATH does not disclose the specific block copolymers described for the current invention.

As a particular comment on Claim 8, the Examiner notes that KAMATH “does not appear to disclose elongation break data” and the KAMATH “copolymer has the same degree of elongation.” (Office Action, page 6). This conjecture is unsubstantiated and is further believed to be unsupported in view of the current amendments to the Claims.

As a particular comment on Claim 9, the explanation of the rejection is not understood and clarification is requested if the rejection is maintained.

As a particular comment on the statement in the Office Action (page 7) that “Regarding the transition temperatures, in view that the same polymer blocks are disclosed, the glass

transition temperatures must also be the same”, further explanation of this rejection is also requested if this rejection is maintained.

For at least the above reason, withdrawal of the rejection over KAMATH is requested.

Rejection Under 35 U.S.C. §103(a) Based on KUMAR in View of KAMATH

Claims 10-16, 18-19 and 21-23 are rejected under 35 U.S.C. §103(a) based on KUMAR in view of KAMATH. This rejection is traversed for the reasons discussed above for KAMATH, and also in view of the following reasons.

With regard to the subject matter previously contained in Claim 10 (now cancelled but added to amended Claim 1), this rejection is believed to be moot in view of the amendments to the Claims listed above. Moreover, the Examiner states in the current Office Action that KAMATH “does not expressly teach that the copolymer of the implantable device is a block copolymer comprising siloxane units and a block of elevated non-siloxane units.” (Office Action, page 8). The Examiner relies on KUMAR to solve this deficiency, but this logic fails.

KUMAR is cited to rectify the deficiency in KAMATH and to provide support for polysiloxane-block copolymers being well known (see Office Action, page 8). However, the combination of KAMATH and KUMAR does not teach or suggest the present invention as presently claimed.

KUMAR teaches selected vinyl-siloxane block copolymers, in particular, “novel siloxane iniferter compounds, block copolymers made therewith, and a method of making the block copolymers.” (Abstract) (emphasis added). The siloxane iniferter compounds can be represented by the formula T-X-Si(R₁)(R₂)-O-(-Si(R₃)(R₄)-O-)_m- Si(R₅)(R₆)-Y

wherein

T and X are organic groups selected so that the T-X bond is capable of dissociating upon being subjected to an appropriate energy source to form a terminator free radical of the formula T and an initiator free radical.

r₁ [sic], R₂, R₅ and R₆ are monovalent moieties selected from the group consisting of hydrogen, C₁₋₄ alkyl, C₁₋₄ alkoxy and aryl which can be the same or are different; R₃ and R₄ are monovalent moieties which can be the same or different selected from the group consisting of hydrogen, C₁₋₄ alkyl, C₁₋₄ fluoroalkyl including at least one fluorine atom and aryl;

Y is selected from the group consistign [sic] of -X-T and -Z wherein X and T are defined above and Z is an organic moiety that will not dissociate to form free radicals when subjected to said energy source; and

m is an integer of at least 10.

The initiator free radical is capable of initiating free radical polymerization of free radically polymerizable monomer. The terminator free radical is insufficiently capable of initiating free radical polymerization of free radically polymerizable monomer but is capable of rejoining with the initiator free radical or a free radical polymer segment free radically polymerized with the initiator free radical.

(See Abstract)

KUMAR further provides:

novel siloxane iniferter compounds which can be used in making tailor-made vinyl-siloxane block copolymers and a method of making the block copolymers. The control of the polymerization provided by the novel siloxane iniferter compounds permits "tailoring" of the vinyl-siloxane block copolymers so that a wide spectrum of physical properties can be introduced. Polymerization is accomplished by sequential polymerization steps.

The siloxane iniferter compounds of the present invention are "macro" inifers capable of predictably inserting a siloxane segment into a vinyl block copolymer backbone of the AB or ABA type of polymer architecture.

(Col. 4, line 64 – col. 5, line 9.)

KUMAR fails to teach an implantable or insertable medical device having the features described in the present invention, including Claims 11-15, 18-19, 22 and 23, particularly:

An implantable or insertable medical device comprising (a) a therapeutic agent and (b) a polymeric carrier region that comprises said therapeutic agent and which releases said therapeutic agent upon administration to a patient, said polymeric carrier region comprising a silicone block copolymer comprising a plurality of siloxane units and a plurality of non-siloxane units, said block copolymer comprising (i) a block of said siloxane units selected from a polydimethylsiloxane block, a polydiethylsiloxane block, a polymethylethylsiloxane block and a polymethylphenylsiloxane block and (ii) a block of elevated T_g non-siloxane units, wherein the polymeric release region is in the form of a coating layer that covers all or a part of said medical device.

KUMAR provides only a general statement of potential wide-ranging applications for the materials produced according to the synthesis methods disclosed therein, including "release coatings for pressure sensitive adhesives, surface active agents, permselective membranes, impact modifiers, fabric treatments, thermoplastic low temperature elastomers, controlled drug release carriers, packaging, medical tubing, biomedical prostheses [sic], etc." (KUMAR, col. 4, lines 53-60.) There is no disclosure of an actual drug or therapeutic agent in any of the materials disclosed. There is no disclosure of a medical device, either with or without the structural elements of the Applicant's medical device, e.g., a coating as claimed. (In fact, the

only coatings described are release coatings for pressure sensitive adhesives.) The cited passage is a non-enabled and general statement about the future potential for using the disclosed compositions for such varied uses as “controlled drug release carriers,” “pressure sensitive adhesives,” and “fabric treatments” and is by no means sufficiently enabled as a basis for rejecting the claimed invention. Indeed, the reference offers no guidance about how to make and to use the disclosed compositions to achieve controlled delivery of drugs.

With regard to Claim 32, KAMATH recites the need to use barrier layers to control the release of the bioactive agent and teaches: “a barrier layer positioned over the composite layer and being of thickness adequate to provide a controlled release of the bioactive agent” (See KAMATH, Abstract). KUMAR does not use a barrier layer and, in fact, relies on its tailored copolymers to provide any needed properties.

Any attempted combination of KAMATH with KUMAR could only be based on impermissible hindsight reconstruction. Moreover, since KUMAR does not teach or suggest any polymeric release region is in the form of a coating layer, these references are simply not combinable. Thus, to make such a combination and draw a conclusion of obviousness could only be based on the use of undue hindsight, which has long been held to be impermissible. MPEP 2142, second paragraph, and the cases cited therein. *See especially, Akso N.V. v. U.S. International Trade Commission*, 808 F.2d 1241, 1480-81, 1 U.S.P.Q.2d, 1241, 1246 (Fed. Cir. 1986), *cert. denied*, 482 U.S. 909 (1987), *Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 874, 228 U.S.P.Q. 90-99 (Fed. Cir. 1985).

Rejection Under 35 U.S.C. §103(a) Based on KAMATH in View of ZUKOWSKY

Claim 20 is rejected under 35 U.S.C. § 103(a) based on KAMATH in view of ZUKOWSKY. This rejection is respectfully traversed for the reasons discussed above and also for the following reasons.

It is the Examiner’s position that although KAMATH does not disclose sterilization, that “in view that the device is a medical device, some sort of sterilization is inherent.” (Office Action, page 10.)

ZUKOWSKY teaches a very specific composition, in particular:

The compositions of the invention comprise a polymeric composition which comprises, and in which the polymeric component preferably consists essentially of:

(a) 5 to 40%, preferably 7 to 28%, of a thermoplastic polymer comprising units derived from an olefin,

(b) 1 to 10% of a polymeric component consisting essentially of 2 to 70% by weight of siloxane units, and at least 20% by weight of other units which are connected into a polymer backbone through a carbonate, urethane or amide linkage, and

(c) 55 to 94%, preferably 62 to 92%, of an elastomer having a Shore D Hardness of less than 60,

the amounts of components (a), (b) and (c) being by weight, based on the total weight of (a), (b) and (c).

(Col. 1, lines 33-46) (emphasis added).

The compositions of ZUKOWSKY are not the compositions of the present invention. Moreover, the compositions of ZUKOWSKY do not provide the elements of the invention missing from KAMATH. Also, in contrast to the present invention ZUKOWSKY does not teach or suggest a polymeric release region in the form of a barrier layer or coating layer.

The current Office Action describes ZUKOWSKY as “disclos[ing] that the polysiloxane copolymers similar to that which are used in Kamath may be radiation sterilized” (Office Action, page 10). However, ZUKOWSKY does not teach or suggest the elements of the invention as described above. Moreover, the fact that KAMATH has a barrier layer and the effect of ZUKOWSKY’s sterilization process on the barrier layer in KAMATH has not been addressed by the Examiner. Any combination of KAMATH with ZUKOWSKY could only be done with impermissible hindsight and, even then, would not give the current invention.

For at least these reasons, Applicants respectfully submit that the claims of the invention discussed above patentable over the cited references. Given the above remarks and the amendments to the claims, Applicant states that the Examiner’s rejections under 35 U.S.C §103(a) have been obviated and Applicant respectfully requests that the Examiner withdraw the rejections.

CONCLUSION

Applicant submits that Claims 1, 5-9, 11-16, 18-20, 22, 23, and 28-32 are in condition for allowance, early notification of which is earnestly solicited. Entry of this Amendment and Response is respectfully requested as it will put the case in a form for allowance or in better

form for an appeal. It is believed that this Amendment and Response is being submitted in time for an Advisory Action should the Examiner require further changes to the Claims. Should the Examiner be of the view that an interview would expedite consideration of this Response or of the application at large, the Examiner is requested to telephone the Applicant's attorney at the number listed below in order to resolve any outstanding issues in this case.

Respectfully submitted,

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